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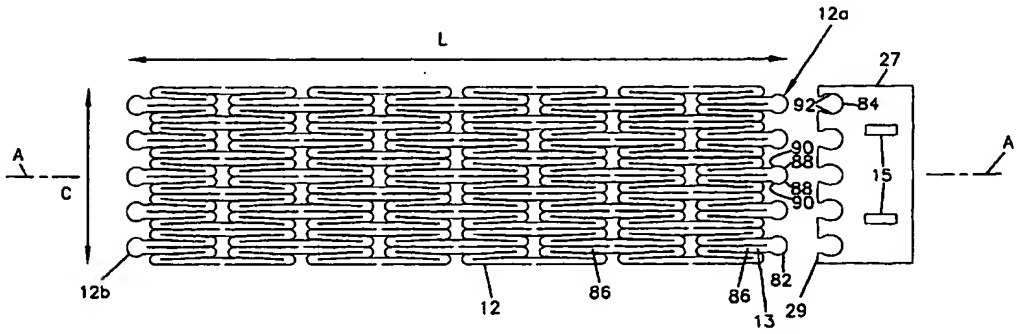

(57) Abstract: An implant delivery system is disclosed. The delivery system includes an elongated member having an implant mounting location. A self-expandable implant is mounted at the implant mounting location. The implant is held in a compressed orientation by a retractable sheath. An interlock structure prevents the implant from deploying prematurely as the sheath is retracted.

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IMPLANT DELIVERY SYSTEM WITH INTERLOCK

This application is being filed as a PCT international patent application in the name of IntraTherapeutics, Inc., a U.S. national corporation, on 01 February 2002, designating all countries except the U.S.

BACKGROUND OF THE INVENTION

Field of Invention

This invention pertains to a system for delivering an implant to a site in a body lumen. More particularly, this invention pertains to a delivery system for a self-expandable implant such as a stent.

Description of the Prior Art

Stents are widely used for supporting a lumen structure in a patient's body. For example, stents may be used to maintain patency of a coronary artery, other blood vessels or other body lumen.

Stents are commonly metal, tubular structures. Stents are passed through a body lumen in a collapsed state. At the point of an obstruction or other deployment site in the body lumen, the stent is expanded to an expanded diameter to support the lumen at the deployment site.

In certain designs, stents are open-celled tubes that are expanded by inflatable balloons at the deployment site. This type of stent is often referred to as a "balloon expandable" stent. Other stents are so-called "self-expanding" stents. Self-expanding stents do not use balloons to cause the expansion of the stent. An example of a self-expanding stent is a tube (e.g., a coil tube or an open-celled tube) made of an elastically deformable material (e.g., a superelastic material such a nitinol). This type of stent is secured to a stent delivery device under tension in a collapsed state. At the deployment site, the stent is released so that internal tension within the stent causes the stent to self-expand to its enlarged diameter. Other self-expanding stents are made of so-called shape-memory metals. Such shape-memory stents experience a phase change at the elevated temperature of the human body. The phase change results in expansion from a collapsed state to an enlarged state.

A delivery technique for elastically deformable stents is to mount the collapsed stent on a distal end of a stent delivery system. Such a system would include an outer tubular member and an inner tubular member. The inner and outer tubular members are axially slideable relative to one another. The stent (in the collapsed state) is mounted surrounding the inner tubular member at its distal end. The outer tubular member (also called the outer sheath) surrounds the stent at the distal end.

Prior to advancing the stent delivery system through the body lumen, a guide wire is first passed through the body lumen to the deployment site. The inner tube of the delivery system is hollow throughout its length such that it can be advanced over the guide wire to the deployment site.

The combined structure (i.e., stent mounted on stent delivery system) is passed through the patient's lumen until the distal end of the delivery system arrives at the deployment site within the body lumen. The deployment system may include radiopaque markers to permit a physician to visualize positioning of the stent under fluoroscopy prior to deployment.

At the deployment site, the outer sheath is retracted to expose the stent. The exposed stent is now free to self-expand within the body lumen. Following expansion of the stent, the inner tube is free to pass through the stent such that the delivery system can be removed through the body lumen leaving the stent in place at the deployment site.

In prior art devices, the stent may prematurely deploy as the outer tube is retracted. Namely, with the outer tube partially retracted, the exposed portion of the stent may expand resulting in the remainder of the stent being squeezed out of the outer tube. This can result in the stent being propelled distally beyond a desired deployment site. Also, once the stent is partially unsheathed, it is sometimes determined that the stent placement needs to be adjusted. With existing systems, this is difficult since the stent has a tendency to force itself out of the sheath thereby making adjustments difficult. What is needed is a system that retains the stent on the catheter even when a majority of the stent has been exposed by retraction of the sheath. What is also needed is a system that allows a stent to be re-sheathed even after a majority of the stent has been exposed by retraction of the sheath.

SUMMARY OF THE INVENTION

One embodiment of the present invention relates to an implant delivery system that provides enhanced placement control of the implant.

A variety of advantages of the invention will be set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practicing the invention. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation view of a stent delivery system according to the present invention;

Fig. 2A is an enlarged cross-sectional view of detail A of Fig. 1 with the stent in a compressed orientation;

Fig. 2B is an enlarged cross-sectional view of detail A of Fig. 1 with the stent in a deployed (i.e., expanded) orientation;

Fig. 3 is an enlarged cross-sectional view of detail B of Fig. 1;

Fig. 4 is an enlarged cross-sectional view of detail C;

Fig. 5 is a cross-sectional view of the inner and outer tubular members of the stent delivery system of Fig. 1 taken along section line 5-5 of Fig. 3;

Fig. 6A is a plan view of a first stent having an interlock structure that interlocks with an interlock structure of a mating collar, the stent and the collar are shown cut longitudinally and laid flat with an axial separation between the stent proximal end and the mating collar;

Fig. 6B is the view of Fig. 6A with the stent proximal end and mating collar shown interlocked;

Fig. 6C is an end view of the stent of Figs. 6A and 6B in its tubular configuration;

Fig. 7 is a laid flat, plan view of a second stent having an interlock structure that interlocks with an interlock structure of a mating collar, the collar includes rotational positioning indicators;

Fig. 8 is a laid flat, plan view of a third stent having an interlock structure that interlocks with an interlock structure of a mating collar, the collar includes rotational positioning notches;

Fig. 9 is a laid flat, plan view of a fourth stent having an interlock structure that interlocks with an interlock structure of a mating collar, the stent and the collar include a rotational alignment key and keyway;

Fig. 10 is a laid flat, plan view of a fifth stent having an interlock structure that interlocks with an interlock structure of a mating collar;

Fig. 11 is a laid flat, plan view of a sixth stent having an interlock structure that interlocks with an interlock structure of a mating collar;

Fig. 12 is a laid flat, plan view of a seventh stent having an interlock structure that interlocks with rectangular posts formed on an inner body of a catheter;

Fig. 13 is a laid flat, plan view of a eighth stent having an interlock structure that interlocks with an interlock structure of a mating collar;

Fig. 14A is a laid flat, plan view of a ninth stent having an interlock structure that interlocks with outwardly projecting line-like projections formed on the inner body of a catheter;

Fig. 14B shows the stent of Fig. 14A interlocked with the line-like projections;

Fig. 15A is a laid flat, plan view of a tenth stent having an interlock structure that interlocks with outwardly projecting posts formed on the inner body of a catheter;

Fig. 15B shows the stent of Fig. 15A interlocked with the posts; and

Figs. 16A and 16B show another delivery system that is an embodiment of the present invention.

DETAILED DESCRIPTION

With reference now to the various drawing figures in which identical elements are numbered identically throughout, a description of a preferred embodiment of the present invention will now be provided.

With initial references to Figs. 1 - 4, a stent delivery system 10 is shown. The stent delivery system 10 is for delivery of a stent 12 to a deployment site in a body lumen of a patient's body. By way of non-limiting, representative example,

the stent 12 may be a self-expanding stent having a construction such as that shown in U.S. Pat. No. 6,132,461. In one non-limiting embodiment, the stent can be made of a superelastic metal such as nitinol, or the like. The stent 12 may also be a coil stent or any other self-expanding stent. The stent 12 includes a proximal end 12a and a distal end 12b. Another representative stent is shown in United States patent application Serial No. 09/765,725, filed January 18, 2001 and entitled STENT, which is hereby incorporated by reference.

The stent 12 is carried on the stent delivery system 10 in a collapsed (or reduced diameter) state as shown in Fig. 2A. Upon release of the stent 12 from the stent delivery system 10 (as will be described), the stent 12 expands to an enlarged diameter (see Fig. 2B) to abut against the walls of the patient's lumen in order to support patency of the lumen.

The stent delivery system 10 includes an inner tubular member 14 (i.e., also referred to as an elongated member) and an outer tubular member 16. Both of the inner and outer tubular members 14 and 16 extend from proximal ends 14a, 16a to distal ends 14b, 16b.

The outer tubular member 16 is sized to be axially advanced through the patient's body lumen. The tubular member 16 is preferably sufficiently long for the distal end 16b to be placed near the deployment site in the patient's body lumen with the proximal end 16a remaining external to the patient's body for manipulation by an operator. By way of example, the outer tubular member 16 (also referred to as a sheath) may be a braid-reinforced polyester of tubular construction to resist kinking and to transmit axial forces along the length of the sheath 16. The outer tubular member 16 may be of widely varying construction to permit varying degrees of flexibility of the outer tubular member 16 along its length.

As shown in Fig. 3, the proximal end 16a of the outer tubular member 16 is bonded to a manifold housing 20. The manifold housing 20 is threadedly connected to a lock housing 22. A strain relief jacket 24 is connected to the manifold housing 20 and surrounds the outer tubular member 16 to provide strain relief for the outer tubular member 16.

The inner tubular member 14 is preferably formed of nylon but may be constructed of any suitable material. As shown in Fig. 2B, the inner tubular member 14 defines a stent attachment location 26 (i.e., a stent mounting location). The inner tubular member 14 also includes markers 27, 28 that are attached to an outer surface

of the inner tubular member 14 (e.g., by techniques such as adhesive, heat fusion, interference fit, fasteners, intermediate members or other techniques). The attachment location 26 is positioned between the markers 27, 28. The radiopaque markers 27, 28 permit a physician to accurately determine the position of the stent attachment location 26 within the patient's lumen under fluoroscopic visualization. As will be described later in the specification, in some embodiments, at least one of the markers 27, 28 forms a collar including a geometry that interlocks with the stent 12 to prevent axial movement of the stent 12 relative to the inner tubular member during transport and deployment of the stent 12. Materials for making the radiopaque marker should have a density suitable for visualization through fluoroscopic techniques. Exemplary materials comprise tanalum, platinum, gold, tungsten and alloys of such metals. In some embodiments, the markers can be coated with a radiopaque material or filled with a radiopaque filler.

A tapered and flexible distal tip member 30 is secured to the distal end 14b of the inner tubular member 14. The highly flexible distal tip member 30 permits advancement of the stent deployment system 10 through the patient's lumen and minimizes trauma to the walls of the patient's lumen. As shown in Fig. 2B, the inner tubular member 14 preferably extends completely through the stent 12 when the stent 12 is mounted at the attachment location 26.

As best shown in Figs. 3 and 4, the inner tube 14 passes through both the manifold housing 20 and lock housing 22. A stainless steel jacket 32 surrounds and is bonded to the inner tubular member 14.

At the inner tube proximal end 14a, a port housing 34 is bonded to the stainless steel jacket 32. The port housing 34 has a tapered bore 36 aligned with an inner lumen 38 of the tubular member 14. The inner lumen 38 extends completely through the inner tubular member 14 so that the entire delivery system 10 can be passed over a guide wire (not shown) initially positioned within the patient's lumen. Opposing surfaces of the inner and outer tubular members 14 and 16, define a first lumen 40 (best seen in Fig. 5). As described in United States patent application Serial No. 09/765,719 filed on January 18, 2001 and entitled STENT DELIVERY SYSTEM WITH SPACER MEMBER, which is hereby incorporated by reference, splines 18 can be provided between the inner and outer tubular members 14 and 16.

As shown in Fig. 3, the manifold housing 20 carries an admission port 42 for injecting a contrast media into the interior of the manifold housing 20. The interior

of the manifold housing 20 is in fluid flow communication with the first lumen 40. Discharge ports 41 (shown in Figs. 2A and 2B) are formed through the outer tubular member 16 to permit contrast media to flow from the first lumen 40 into the patient's body lumen.

As shown in Fig. 3, an O-ring 44 surrounds the stainless steel jacket 32 between the manifold housing 20 and lock housing 22. Upon threaded connection of the manifold housing 20 to the lock housing 22, the O-ring 44 compresses against the stainless steel jacket 32 in sealing engagement to prevent contrast media from flowing in any path other than through the first lumen 40.

As shown in Figs. 1 and 3, the lock housing 22 carries a threaded locking member (or lock nut) 46 which can be turned to abut the stainless steel jacket 32. The lock nut 46 can be released to free the stainless steel jacket to move axially. According, when the lock nut 46 engages the jacket 32, the jacket 32 (and attached inner tubular member 14) cannot move relative to the lock housing 22, manifold housing 20 or the outer tubular member 16. Upon release of the lock nut 46, the inner tubular member 14 and outer tubular member 16 are free to slide axially relative to one another between a transport position and a deploy position.

First and second handles 48, 50 are secured to the lock housing 22 and jacket 32, respectively. In the transport position (shown in Fig. 2A), the handles 48, 50 are spaced apart and the distal end of the outer tubular member 16 forms a sheath that covers the stent attachment location 26 to prevent premature deployment of the stent 12. When the handle 48 is pulled rearwardly toward the handle 50, the outer tubular member 16 slides rearwardly or proximally relative to the inner tubular member 14. Preferably, the outer tubular member 16 slides rearwardly a distance sufficient to fully expose the stent attachment location 26 and permit the stent 12 to freely expand toward its fully expanded diameter (see Fig. 2B). After such expansion, the stent delivery system can be proximally withdrawn through the expanded stent and removed.

As shown in Fig. 3, the first handle 48 is rotatably mounted on a flange 22a of the lock housing 22. The first handle 48 surrounds the stainless steel jacket 32 and is freely rotatable about the longitudinal axis of the jacket 32 and freely rotatable about the flange 22a. The first handle 48 is axially affixed to the lock housing 22 such that axial forces applied to the first handle 48 are transmitted through the lock housing 22 and manifold housing 20 to the outer tubular member

16 to axially move the outer tubular 16. However, rotary action of the first handle 48 about the axis of the stainless steel jacket 32 is not transmitted to the housings 20, 22 or to the outer tubular member 16 by reason of the free rotation of the first handle 48 on flange 22a.

As shown in Fig. 4, the second handle 50 is mounted on an anchor 52 that is bonded to the stainless steel jacket 32 through any suitable means (such as by use of adhesives). The anchor 52 includes a flange 52a that is radial to the axis of the stainless steel jacket 32. The second handle 50 is mounted on the flange 52a and is free to rotate on the anchor 52 about the axis of the stainless steel jacket 32. However, axial forces applied to the handle 50 are transmitted to the stainless steel jacket 32 which, being bonded to the inner tubular member 14, results in axial movement of the inner tubular member 14.

With the handle construction described above, relative axial movement between the handles 48, 50 results in relative axial movement between the inner and outer tubular members 14, 16. Rotational movement of either of the handles 48, 50 does not affect rotational positioning of the inner or outer tubular members 14, 16 and does not affect axial positioning of the inner and outer tubes 14, 16.

The free rotation of the handles 48, 50 results in ease of use for a physician who may position his or her hands as desired without fear of interfering with any axial positioning of the inner and outer tubular members 14, 16. The spacing between the handles 48, 50 is equal to the stroke between the transport position and the deploy position of the tubular members 14, 16. As a result, the spacing permits the operator to have ready visual indication of the relative axial positioning between the inner and outer tubular members 14, 16. This relative axial positioning can be fixed by engaging the lock nut 46. In any such positioning, contrast media can be injected through the admission port 42 into the chamber 40 with the contrast media flowing out of the side ports 41 into the body lumen to permit visualization under fluoroscopy.

With stent deployment systems having premounted stents of various axial lengths, the positioning of the second handle 50 on the stainless steel jacket 32 can be selected at time of assembly so that a spacing S (see Fig. 1) between the handles 48, 50 corresponds to the length of the stent 12 carried on the stent deployment system. For example, in a preferred embodiment, the spacing S is about 10 millimeters longer than the deployed length of the stent. Accordingly, the user will

know that the outer tubular member 16 has been fully retracted when the handles 48, 50 have been pushed completely together to completely release the stent 12. Also, the freely rotatable handles 48, 50 are easy to hold from any angle without slippage. The lock nut 46 ensures that the stent 12 will not deploy prematurely.

A concern with existing delivery systems for self-expanding stents is control of stent delivery. For example, due to their elastic characteristics, self-expanding stents have a tendency to propel themselves axially outwardly from their restraining sheaths before the sheaths have been completely retracted. When this occurs, control of stent placement is compromised since the stent may overshoot the desired deployment site. Further, once the stent has been completely deployed, subsequent adjustment of the stent deployment location can be difficult because re-sheathing typically cannot be readily accomplished.

To address the above concerns, the delivery system 10 is preferably equipped with an interlock configuration that constrains relative axial movement between the stent 12 and the inner tube 14 until after the sheath 16 has been fully retracted. For example, when the stent 12 is mounted on the inner tube 14 and restrained in the compressed orientation by the sheath 16 as shown in Fig. 2A, a first interlock geometry (e.g., male interlock structures 82 as shown in Fig. 2A) located at the proximal end of the stent 12 interlocks with a second interlock geometry (e.g., female interlock structures 84 as shown in Fig. 2A) defined by the proximal marker 27 (also referred to as a collar). The interlock geometries remain interlocked to constrain axial movement of the stent 12 until after the sheath has been retracted beyond a predetermined location (e.g., the proximal-most end 12a of the stent 12). When the sheath 12 has been retracted beyond the predetermined location, the interlock geometry of the stent 12 is allowed to expand. As the interlock geometry of the stent expands, the interlock geometry of the stent disengages from the interlock geometry of the marker 27 thereby allowing the inner tube 14 of the catheter to be moved axially relative to the stent without interference from the interlock geometries.

Figs. 6A and 6B illustrate the proximal end 12a of the stent 12 in relation to the marker 27 located at the proximal end of the attachment location 26. In Figs. 6A and 6B, the stent 12 and the marker 27 have been cut longitudinally and laid flat. The stent 12 has a length L and a circumference C. In Fig. 6A, the marker 27 and the stent 12 are shown disengaged from one another. In Fig. 6B marker 27 and the

stent 12 are shown interlocked. In both Figs. 6A and 6B, the stent is in the reduced diameter configuration. Similarly, the stents depicted in Figs. 7-15B are shown in the reduced diameter orientation.

Referring to Fig. 6A, the stent 12 includes a plurality of struts 86 (i.e., reinforcing members). At least some of the struts 86 have free terminal ends that define the proximal and distal ends 12a and 12b of the stent 12. Male interlock structures 82 (i.e., keys) are provided at the free terminal ends of the struts 86. As shown in Fig. 6A, the male interlock structures 82 include enlargements in the form of circular projections. The circular projections include interlock portions 88 that project outwardly from the struts 86 in a circumferential direction (i.e., in a direction coinciding with the circumference C of the stent 12). The interlock portions 88 include interlock surfaces 90 that face in an axial direction. The phrase "face in an axial direction" will be understood to mean that least a vector component of the surface 90 is perpendicular with respect to a longitudinal axis A-A of the stent 12. Thus, the surface 90 need not be completely perpendicular relative to the longitudinal axis of the stent 12 to be construed as facing in an axial direction. In other words, a surface aligned at oblique angle relative to the longitudinal axis of the stent 12 shall also be construed as facing in an axial direction since such surface has a vector component that is perpendicular relative to the longitudinal axis of the stent.

As best shown schematically in Fig. 6C, the male interlock structures 82 are preferably positioned within a region defined between an inner diameter D1 and an outer diameter D2 of the stent 12. This is preferably true regardless of whether the stent 12 is in the expanded diameter orientation or the reduced diameter orientation. Preferably, at least portions of the interlock surfaces 90 are located within 5 millimeters of the proximal end 12a of the stent 12. More preferably, at least portions of the interlock surfaces 90 are located within 3 millimeters of the proximal end 12a of the stent 12. Most preferably, at least portions of the interlock surfaces 90 are located within 2 millimeters of the proximal end 12a of the stent 12.

Referring to Fig. 6A, the stent 12 includes a lumen reinforcing structure including a plurality of struts 13 adapted to define open cells 15 (best shown in Fig. 2B) when the stent 12 is deployed. Preferably, the male interlock structures 82 are located within 5 millimeter of the struts 13 that define the open cells 15. More preferably, the male interlock structures 82 are located within 4, 3 or 2 millimeters of the struts 13 that define the open cells 15. Most preferably, the male interlock

structures 82 are located within 1 millimeter of the struts 13 that define the open cells 15. Because the male interlock structures 82 are located relatively close to the structure defining the open cells 15, during deployment of the stent 12, the male interlock structures 82 will expand radially outwardly simultaneously with the radial expansion of at least a portion of the cell defining structure. When the stent 12 is expanded, the interlock structures 82 are preferably maintained generally within a boundary defined by the inner and outer diameters of the cell defining portion of the stent, and preferably the interlock structures 82 are not biased or angled radially outwardly relative to the cell defining portion.

Still referring to Figs. 6A and 6B, the marker 27 has an axial distal edge 29 facing the proximal end 12a of stent 12. Female interlock structures 84 (i.e., sockets, openings, keyways, etc.) are defined by the marker 27 adjacent the edge 29. The female interlock structures 84 are configured to have a complimentary mating geometry with respect to the male interlock structures 82 of the stent 12. For example, similar to the male interlock structures 82, the female interlock structures 84 are shown having generally rounded or circular shapes. Each of the female interlock structures 84 includes interlock surfaces 92 that face in an axial direction.

The geometry of the female interlock structures 84 is selected to mate with the predetermined geometry of the stent proximal end 12a such that the stent 12 and the marker 27 can be axially coupled or interlocked when the stent 12 is compressed at the mounting location 26. When the male and female interlock structures 82 and 84 are interlocked, the interlock surfaces 90 and 92 oppose and circumferentially overlap one another (see Fig. 6B) such that the stent is restricted from distal movement relative to the marker 27.

With the specific embodiment shown, the stent 12 and collar 27 are rotary coupled such that the stent 12 and collar 27 are restricted from relative rotary motion (i.e., about axis X – X) when the stent 12 is in the collapsed state. The predetermined stent geometry of the interlock structures 82 and the complementary mating geometry of the collar 27 do not restrict relative radial motion. Namely, as the self-expanding stent 12 expands radially, the male interlock structures 82 are free to radially move out of the female interlock structures 84. After such motion, the stent 12 is no longer coupled to the collar 27 and the stent 12 and collar 27 are free to move axially, radially or transversely to one another.

With the embodiment thus described, the mating features of the stent 12 and collar 27 prevent premature discharge of the stent 12 from a stent attachment location 26. As the outer sheath 16 is retracted, the sheath distal end 16b exposes the distal end 12b of the stent 12. At this point, the exposed distal end 12b of the stent 12 is free for limited expansion restrained by the remainder of the stent 12 being covered by the sheath 16 and by the attachment of the stent proximal end 12a to the proximal marker 27.

Further retraction of the sheath 16, permits still further expansion of the stent 12. As the sheath distal end 12b approaches the stent proximal end 12a, the expansion of the stent material tends to urge the stent 12 to squeeze out of the small portion of the sheath 16 now covering the stent 12. However, this propensity is overcome by the attachment of the stent proximal end 12a to the collar 27 since any such ejection of the stent 12 would require axial separation of the stent 12 and collar 27. Such movement is prevented by the male interlock structures 82 and the female interlock structures 84.

Therefore, as long any portion of the sheath 16 overlies the male and female interlock structures 82 and 84, the proximal end 12a of the stent 12 cannot expand and cannot axially move away from the collar 27. Accordingly, the stent 12 is not released from the attachment location 26 until the physician has fully retracted the sheath 16 with the sheath distal end 16b retracted proximal to the proximal end of stent attachment location 26. The sheath distal end 16b is provided with a marker 16b' (shown in Figs. 2A and 2B) to permit visualization of the relative position of the sheath distal end 12b and the markers 27, 28 of the stent attachment location 26.

With the structure and operation thus described, the physician has greater control of the release of the stent 12. More accurate stent positioning is attained. As long as even a small portion of the sheath 16 is not fully retracted (e.g., at least 1 mm extends distally to the proximal end 12a of the stent 12) the axial position of the stent 12 can be adjusted by advancing or retracting the inner tubular member 14. Also, as long as a small portion of the sheath 16 remains covered by the sheath 16 (e.g., at least 1 mm), the stent 12 can be readily re-sheathed by moving the sheath 16 in a distal direction.

In the embodiment of Figs. 6A and 6B, the female and male interlock structures 82 and 84 have complementary mating geometries. It will be appreciated that in alternative embodiments, the female and male interlock structures need not

have complementary/identical shapes. Instead, to provide an interlock, it is only necessary for a portion of the male interlock to be received in the female interlock such that mechanical interference or overlap between the interlocks prevents the interlocks from being axially separated. This can be accomplished without having identical mating shapes.

As described above, the interlock structure 84 of the inner tube 14 is provided on the proximal marker 27. It will be appreciated that the interlock structure 84 need not be the same element as the marker but could be a separate part. As a separate part, the interlock structure could be integrally formed/connected with the exterior of the inner tube 14, connected to the outer surface of the inner tube by conventional techniques (e.g., adhesive, fasteners, fusion bonding, etc.), or be connected to the outer surface of the inner tube 14 by one or more intermediate members. Further, the embodiment of Figs. 6A and 6B shows that the interlock between the stent 12 and the tube 14 is provided at the proximal end 12a of the stent 12b. It will be appreciated that for certain embodiments, the interlock between the inner tube 14 and the stent 12 can be provided at the distal end 12b of the stent 12 (e.g., for a distally retractable sheath). Moreover, while the embodiment of Figs. 6A and 6B shows interlock structures provided at all of the proximal ends of the struts 86, the invention is not so limited. For example, in some embodiments, only some of the struts 86 may include interlock structures. While in certain embodiments it may be desirable to use only one interlock structure at the end of the stent 12, it is preferable to use at least two separate/discrete interlock structures uniformly spaced about the circumference of the stent. It is more preferable to use at least 4 separate/discrete interlock structures that are preferably uniformly spaced about the circumference of the stent.

The collar 27 may be provided with indicia to indicate to a physician the position of the collar 27 (and hence the stent 12) when the combination is in a patient's vessel and is being visualized under fluoroscopy. In the embodiment of Figs. 6A and 6B, the indicia is shown as cutouts 15 in the collar 27. Fig. 7 shows a collar 27' having indicia in the form of proximal projections 15' off of the proximal edge of the collar 27'. Fig. 8 shows a collar 27'' having indicia in the form of triangular notches 15'' defined at the proximal edge of the collar 27''. In the embodiments shown, the indicia 15, 15' and 15'' are spaced apart circumferentially on their respective collars 27, 27' and 27'' so that the indicia are 180 degrees apart.

In the embodiment of Figs. 6A and 6B, the pattern and shape of the male interlock structures 82 and the female interlock structures 84 are symmetrical about the stent axis X – X. As a result, the stent 12 can be affixed to the collar 27 in any one of a plurality of rotary alignments about axis X – X.

Fig. 9 illustrates an embodiment of a collar 127 and stent 112 where the symmetrical pattern is interrupted. In the example of Fig. 9, a single unique key 117 is provided (which, in the example shown, has a square geometry compared to the circular geometry of remaining male interlock structures 182). Similarly, the collar 127 has a unique keyway 117a to mate with the unique key 117. As a result, the stent 112 can only be affixed to the collar 127 in one rotary alignment.

In all of the above embodiments, once the position of a stent is fixed to a collar, a non-symmetrical stent feature (e.g., an opening for placement at a bifurcation in a vessel) can be aligned with the indicia (or, if desired, a single indicia can be provided on the collar). Therefore, a physician can easily visualize the position of any non-symmetrical stent feature.

Fig. 10 illustrates an embodiment of a stent 212 and radiopaque collar 227 having another interlock configuration. The collar 227 has circumferential slots 228 for assisting in adhesively bonding the collar 227 to the outer surface of the inner tube 14. The stent 212 has proximal and distal ends 212a and 212b. The stent also includes proximal end struts 286a having free ends at which male interlock structures 282 are formed. The male interlock structures 282 are formed by notches cut into the proximal end struts 286a. The male interlock structures 282 include axially facing interlock surfaces 290 that face in a distal direction. Preferably, the surfaces 290 are located within 5 millimeters of the proximal end 212a of the stent 212, and within 1, 2, 3, 4 or 5 millimeters of a cell defining portion of the stent.

The collar 227 includes female interlock structures 284 in the form of sockets. The sockets are partially defined by projections adapted to fit within the notches cut into the proximal end struts 286a. The projections define axially facing interlock surfaces 292 that face in a proximal direction. When the male and female interlock structures 282 and 284 are interlocked, the surfaces 290 and 292 oppose one another to prevent the male interlock structures 282 from being axially withdrawn from the female interlock structures 284.

Fig. 11 illustrates an embodiment of a stent 312 and radiopaque collar 327 having another interlock configuration. The collar 327 has circumferential slots 328

for assisting in adhesively bonding the collar 327 to the outer surface of the inner tube 14. The stent 312 has proximal and distal ends 312a and 312b. The stent also includes proximal end struts 386a having free ends at which male interlock structures 382 are formed. The male interlock structures 382 are formed by enlarged heads (i.e., protuberances or keys) located at the ends of the end struts 386a. The male interlock structures 382 include axially facing interlock surfaces 390 that face in a distal direction. Preferably, the surfaces 390 are located within 5 millimeters of the proximal end 312a of the stent 312, and within 1, 2, 3, 4 or 5 millimeters of a cell defining region of the stent. The collar 327 includes female interlock structures 384 in the form of sockets. The female interlock structures 384 include axially facing interlock surfaces 392 that face in a proximal direction. When the male and female interlock structures 382 and 384 are interlocked, the surfaces 390 and 392 oppose one another to prevent the male interlock structures 382 from being axially withdrawn from the female interlock structures 384.

Fig. 12 illustrates an embodiment of a stent 412 including female interlock structures 484. The female interlock structures 484 preferably include distally facing interlock surfaces 492 located within 5 mm of a proximal end 412a of the stent 412 and within 1, 2, 3, 4 or 5 millimeters of a cell defining region of the stent. The female interlock structures 484 are sized to receive male interlock structures 482 in the form of rectangular posts. Preferably, the posts are connected to the outer surface of the inner tube 14 (e.g., integrally or otherwise). The posts define proximally facing interlock surfaces 490. When the female and male interlock structures 484 and 482 are coupled, the surfaces 490 and 492 engage each other to prevent distal movement of the stent 412 relative to the posts.

Fig. 13 illustrates an embodiment of a stent 512 including male interlock structures 582 in the form of hooks. The male interlock structures 582 preferably include distally facing interlock surfaces 590 located within 5 mm of a proximal end 512a of the stent 512 and within 1, 2, 3, 4 or 5 millimeters of a cell defining region of the stent. The male interlock structures 582 are sized to fit within female interlock structures 584 defined by a collar 527. The female interlock structures 584 define proximally facing interlock surfaces 592. When the female and male interlock structures 584 and 582 are coupled, the surfaces 590 and 592 engage each other to prevent distal movement of the stent 512 relative to the collar 527.

Figs. 14A and 14B illustrate an embodiment of a stent 612 including female interlock structures 684 in the form of longitudinal slots between or within struts. The female interlock structures 684 preferably include distally facing interlock surfaces 692 (e.g., defined by the proximal ends of the slots) located within 5 mm of a proximal end 612a of the stent 612 and within 1, 2, 3, 4 or 5 millimeters of a cell defining region of the stent. The female interlock structures 684 are sized to receive male interlock structures 682 in the form of linear posts. Preferably, the posts are connected to the outer surface of the inner tube 14 (e.g., integrally or otherwise). The posts define proximally facing interlock surfaces 690 (e.g., at the proximal ends of the posts). When the female and male interlock structures 684 and 682 are coupled as shown in Fig. 14B, the surfaces 690 and 692 engage each other to prevent distal movement of the stent 612 relative to the posts.

Figs. 15A and 15B illustrate an embodiment of a stent 712 including female interlock structures 784 in the form of circular openings defined through enlarged strut ends of the stent 712. The female interlock structures 784 preferably include distally facing interlock surfaces 792 located within 5 mm of a proximal end 712a of the stent 712 and within 1, 2, 3, 4 or 5 millimeters of a cell defining region of the stent. The female interlock structures 784 are sized to receive male interlock structures 782 in the form of cylindrical posts or pins. Preferably, the posts are connected to the outer surface of the inner tube 14 (e.g., integrally or otherwise). The posts define proximally facing interlock surfaces 790. When the female and male interlock structures 784 and 782 are coupled as shown in Fig. 15B, the surfaces 790 and 792 engage each other to prevent distal movement of the stent 712 relative to the posts.

Figs. 16A and 16B show a stent delivery system 10' that is another embodiment of the present invention. The delivery system 10' includes an inner member 14' and an outer sheath 16'. The inner member 14' includes a flexible distal tip 30' and a stent mounting location 26'. Proximal and distal markers 27' and 28' are located on opposite sides of the mounting location 26'. The proximal marker 27' includes interlock structures in the form of receivers 84' or receptacles. The receivers 84' are adapted to receive and interlock with interlock structures in the form of enlargements 82' provided at the proximal end of self expanding stent 12'. The enlargements 82' are preferably within 1, 2, 3, 4 or 5 millimeters of cell defining structures 83' of the stent 12'.

While the various embodiments of the present invention have related to stents and stent delivery systems, the scope of the present invention is not so limited. For example, while particularly suited for stent delivery systems, it will be appreciated that the various aspects of the present invention are also applicable to systems for delivering other types of self-expandable implants. By way of non-limiting example, other types of self-expanding implants include anastomosis devices, blood filters, grafts, vena cava filters, percutaneous valves, or other devices. Also, while it is preferred for the interlocks of the present invention to be within 5 millimeters of an end of their corresponding implant to enhance deployment control, larger spacings could be used for certain applications. Similarly, while it is preferred for the interlocks to be within 5, 4, 3, 2 or 1 millimeters of cell defining regions of the stents, other spacings could be used in certain alternative embodiments.

It has been shown how the objects of the invention have been attained in a preferred manner. Modifications and equivalents of the disclosed concepts are intended to be included within the scope of the claims.

What is Claimed Is:

1. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

the implant including a first interlock structure and the elongated body including a second interlock structure, the first and second interlock structures interlocking to constrain axial movement of the implant relative to the elongated member when the implant is at least partially within the sheath, and the first and second interlock structures not constraining radial expansion of the implant;

one of the first and second interlock structures including a male interlock structure and the other of the first and second interlock structures including a female interlock structure adapted to receive the male interlock structure when the implant is in the compressed orientation;

the implant including a cell defining region; and

at least a portion of the first interlock structure being positioned within 5 millimeters of the first end of the implant and within 5 millimeters of the cell defining region of the implant.

2. The implant delivery system of claim 1, wherein the implant comprises a stent.

3. The implant delivery system of claim 1, wherein at least a portion of the first interlock structure is positioned within 2 millimeters of the first end of the implant.

4. The implant delivery system of claim 1, wherein the elongated body includes a radiopaque marker positioned adjacent to the implant mounting location, and wherein the marker defines the second interlock structure.

5. The implant delivery system of claim 1, wherein the first end of the implant is a proximal end of the implant.

6. The implant delivery system of claim 1, wherein the implant includes a plurality of separate first interlock structures having at least portions positioned within 5 millimeters of the first end, and wherein the elongated body includes a plurality of second interlock structures for interlocking with the first interlock structures.

7. The implant delivery system of claim 1, wherein the first interlock structure is the male interlock structure and the second interlock structure is the female interlock structure.

8. The implant delivery system of claim 7, wherein the male interlock structure includes an enlargement positioned at the first end of the implant.

9. The implant delivery system of claim 8, wherein the implant includes a plurality of enlargements at the first end of the implant.

10. The implant delivery system of claim 8, wherein the male interlock structure includes a circumferential projection positioned at the first end of the implant.

11. The implant delivery system of claim 10, wherein the implant includes a plurality of the circumferential projections at the first end of the implant.

12. The implant delivery system of claim 1, wherein the first interlock structure is the female interlock structure and the second interlock structure is the male interlock structure.

13. The implant delivery system of claim 12, wherein the implant includes struts, and the female interlock structure includes a post opening defined through at least one of the struts.

14. The implant delivery system of claim 13, wherein the implant includes a plurality of the post openings.

15. The implant delivery system of claim 13, wherein the implant includes struts, and the female interlock structure includes an opening between the struts.

16. The implant delivery system of claim 1, wherein the first interlock structure is within 2 millimeters of the cell defining region of the implant.

17. The implant delivery system of claim 1, wherein the first interlock structure is within 1 millimeter of the cell defining region of the implant.

18. The implant delivery system of claim 1, wherein the elongated member extends completely through the implant.

19. The implant delivery system of claim 1, wherein the cell defining region of the implant includes a boundary defined by an inner diameter and an outer diameter of the implant, and wherein the first interlock structure stays generally within the boundary after the implant has been deployed.

20. The implant delivery system of claim 1, wherein the first interlock structure is not radially outwardly biased relative to the cell defining region of the implant.

21. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

the implant including a cell defining region, the implant also including a plurality of struts at least some of which have terminal ends defining the first end of the implant, the implant also including at least two enlargements positioned at the terminal ends of the struts, the enlargements being located within 5 millimeters of the cell defining region of the implant; and

the elongated body including receptacles that receive the enlargements to constrain axial movement of the implant relative to the elongated member when the implant is at least partially within the sheath.

22. The implant delivery system of claim 21, wherein the elongated body includes a radiopaque marker positioned adjacent to the implant mounting location, and wherein the marker defines the receptacles.

23. The implant delivery system of claim 21, wherein the first end of the implant is a proximal end of the implant.

24. The implant delivery system of claim 21, wherein the enlargements are within 2 millimeters of the cell defining region of the implant.

25. The implant delivery system of claim 21, wherein the enlargements are within 1 millimeter of the cell defining region of the implant.

26. The implant delivery system of claim 21, wherein the elongated member extends completely through the implant.

27. The implant delivery system of claim 21, wherein the cell defining region of the implant includes a boundary defined by an inner diameter and an outer diameter of the implant, and wherein the enlargements stay generally within the boundary after the implant has been deployed.

28. The implant delivery system of claim 21, wherein the enlargements are not radially outwardly biased relative to the cell defining region of the implant.

29. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

the implant including a cell defining region and first and second ends, the implant also including at least two female male interlock structures positioned within 5 millimeters of the first end of the implant and within 5 millimeters of the cell defining region of the implant; and

the elongated body including male interlock structures that are received within the female interlock structures to constrain axial

movement of the implant relative to the elongated member when the implant is at least partially within the sheath, the male and female interlock structures not constraining radial expansion of the implant.

30. The implant delivery system of claim 29, wherein the elongated body includes a radiopaque marker positioned adjacent to the implant mounting location, and wherein the marker includes the male interlock structures.

31. The implant delivery system of claim 29, wherein the first end of the implant is a proximal end of the implant.

32. The implant delivery system of claim 29, wherein the female interlock structures are within 2 millimeters of the cell defining region of the implant.

33. The implant delivery system of claim 29, wherein the female interlock structures are within 1 millimeter of the cell defining region of the implant.

34. The implant delivery system of claim 29, wherein the elongated member extends completely through the implant.

35. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

a marker attached to the elongated member, the marker including structure that interlocks with the implant to constrain axial movement of the implant relative to the elongated member when the implant is at least partially within the sheath.

36. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

the implant including a first interlock structure and the elongated body including a second interlock structure, the first and second interlock structures interlocking to constrain axial movement of the implant relative to the elongated member when the implant is at least partially within the sheath, and the first and second interlock structures not constraining radial expansion of the implant;

one of the first and second interlock structures including a male interlock structure and the other of the first and second interlock structures including a female interlock structure adapted to receive the male interlock structure when the implant is in the compressed orientation; and

at least a portion of the first interlock structure being positioned within 5 millimeters of the first end of the implant, and the elongated member extending through the implant at the implant mounting location.

37. The implant delivery system of claim 36, wherein at least a portion of the first interlock structure is positioned within 2 millimeters of the first end of the implant.

38. An implant delivery system comprising:

a catheter including an elongated member having an implant mounting location;

an expandable implant mounted on the elongated body at the implant mounting location, the implant being expandable from a compressed orientation to an expanded orientation, the implant including first and second ends;

a sheath mounted on the elongated member, the sheath being positionable in a transport position in which the sheath covers the implant mounted at the implant mounting location, the sheath also being positionable in a deploy position in which the implant is exposed;

the implant including a first interlock structure and the elongated body including a second interlock structure, the first and second interlock structures interlocking to constrain axial movement of the implant relative to the elongated member when the implant is at least partially within the sheath, and the first and second interlock structures not constraining radial expansion of the implant;

one of the first and second interlock structures including a male interlock structure and the other of the first and second interlock structures including a female interlock structure adapted to receive the male interlock structure when the implant is in the compressed orientation;

the implant including a cell defining region that includes a boundary defined by an inner diameter and an outer diameter of the implant, the first interlock structure being configured to stay generally within the boundary after the implant has been deployed; and

at least a portion of the first interlock structure being positioned within 5 millimeters of the first end of the implant.

39. The implant delivery system of claim 38, wherein at least a portion of the first interlock structure is positioned within 2 millimeters of the first end of the implant.

40. A method for deploying a self-expandable implant with a deployment system, the deployment system including a sheath for holding the implant in a compressed orientation, the implant including first and second ends, the implant also including an interlock surface positioned between inner and outer diameters of the implant, the interlock surface being located within 5 millimeters of the first end of the implant, the method comprising:

generating relative movement between the implant and the sheath to expose the implant;

engaging the interlock surface with a retainer as the implant is exposed to prevent the implant from prematurely exiting the sheath; and

after the implant has been exposed beyond the interlock surface, disengaging the interlock surface from the retainer by self-expanding the implant, wherein the interlock surface disengages from the retainer simultaneous with the expansion of a cell defining portion of the implant.

41. The method of claim 40, wherein the implant is a stent.

42. The method of claim 40, wherein the interlock surface is within 2 millimeters of the first end of the implant.

43. The method of claim 40, wherein the first end of the implant is a proximal end of the implant and the second end of the implant is a distal end of the implant.

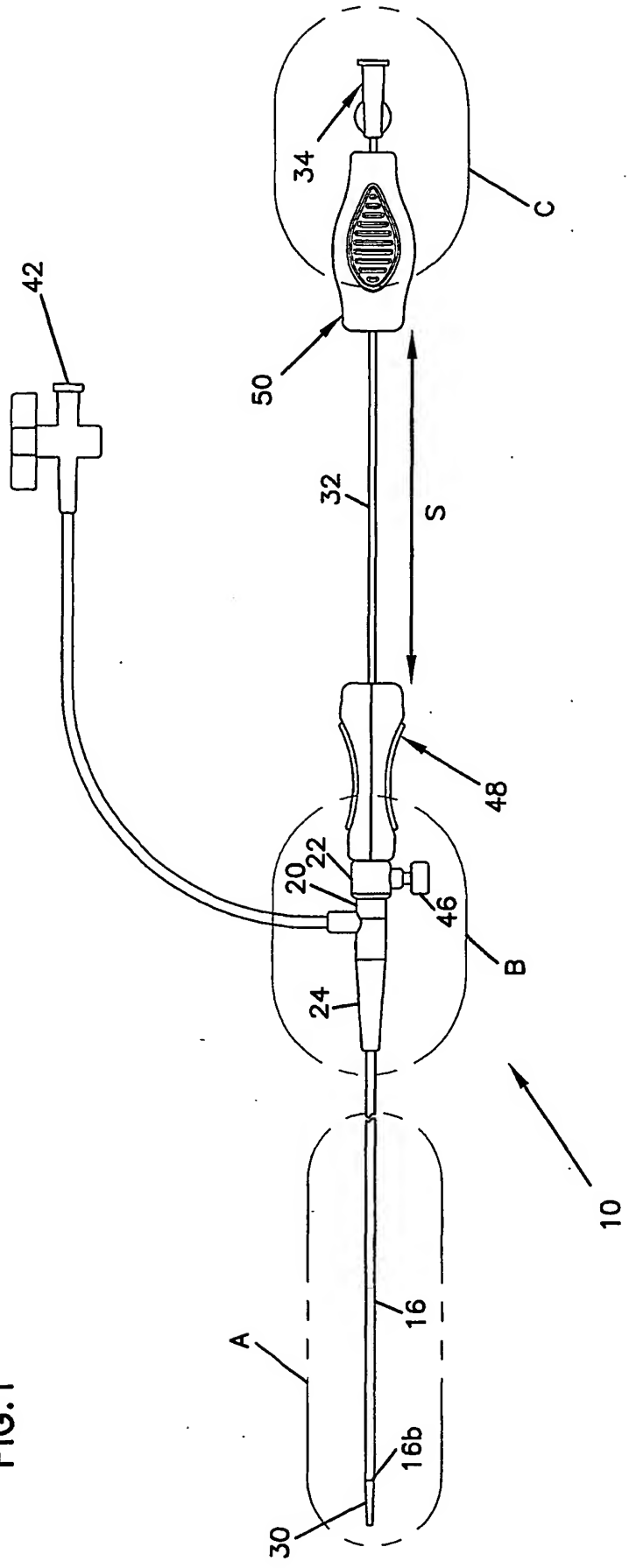
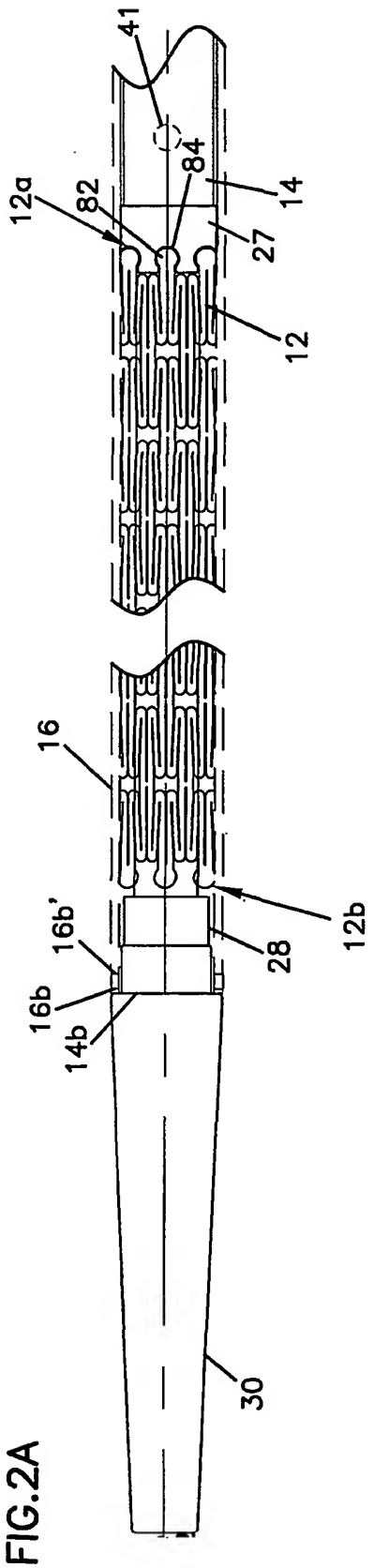


FIG. 1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12a
82
84
14
27
12
16
16b'
28
12b
16b
14b
30

FIG.2A

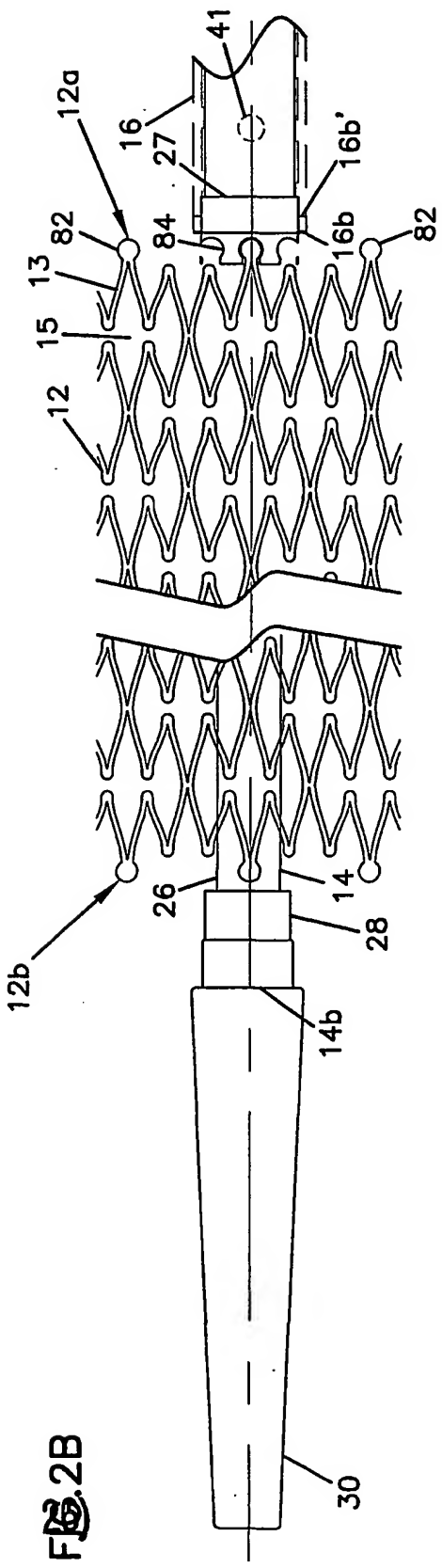

41
12a
16
27
16b'
82
84
16b
82
13
15
12
26
14
28
12b
14b
30

FIG.2B

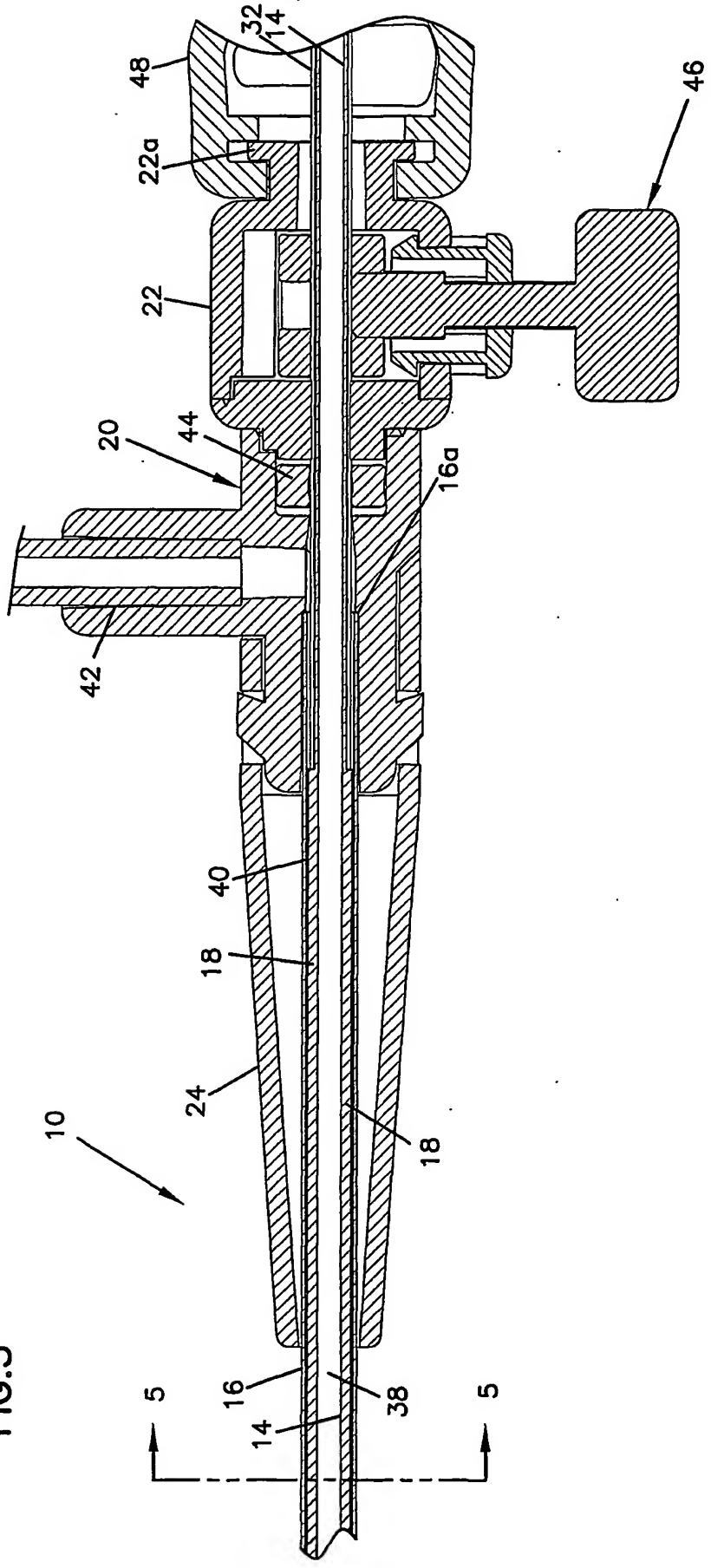


FIG.3

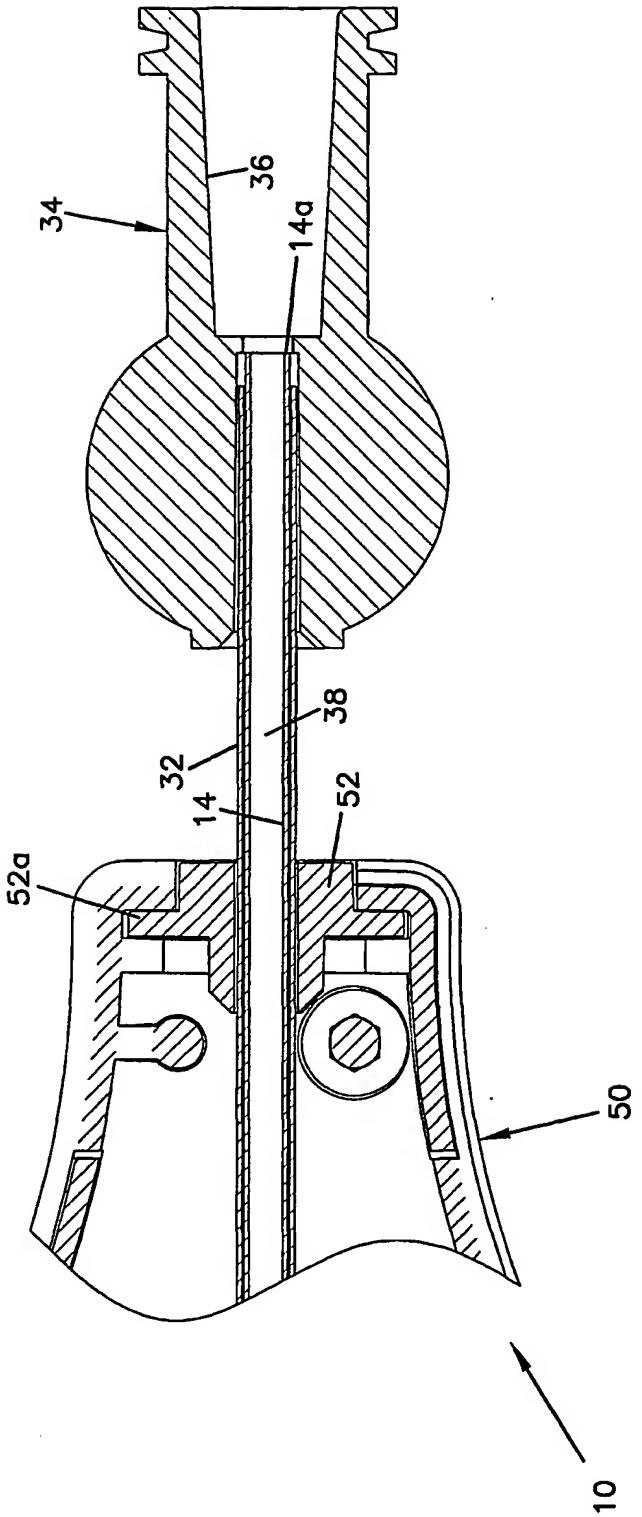


FIG.4

FIG.5

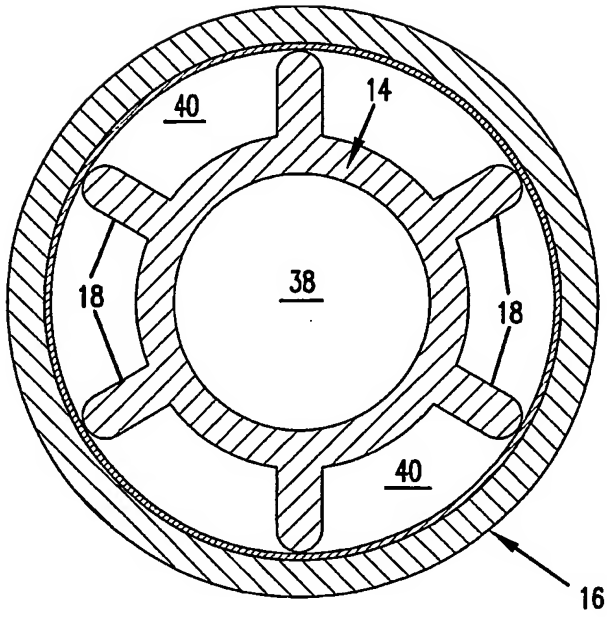
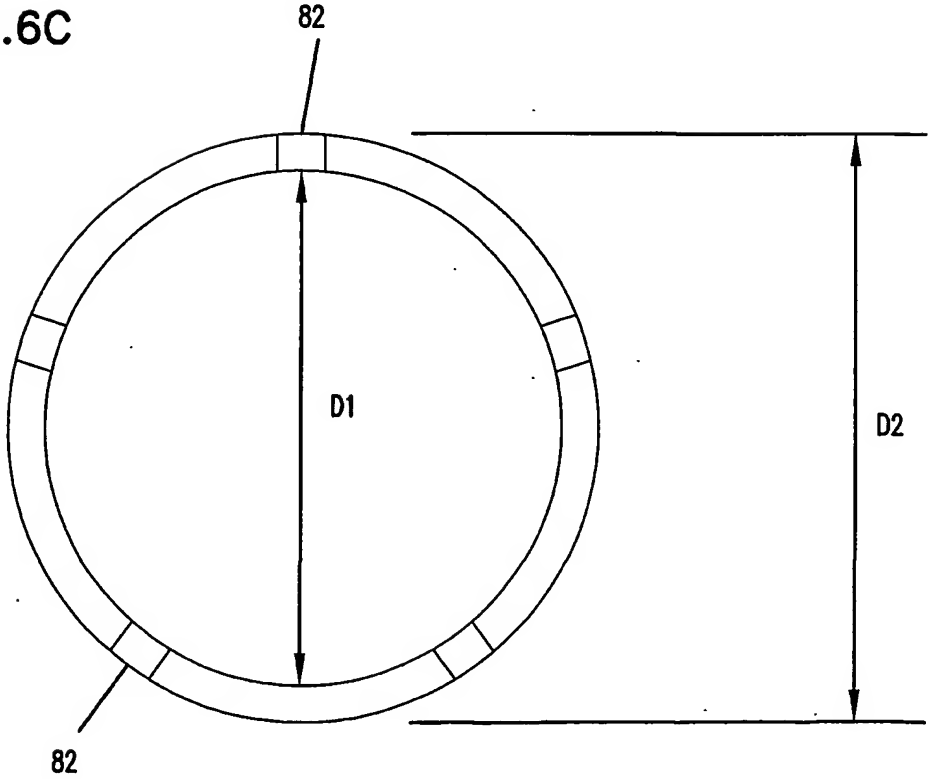


FIG.6C



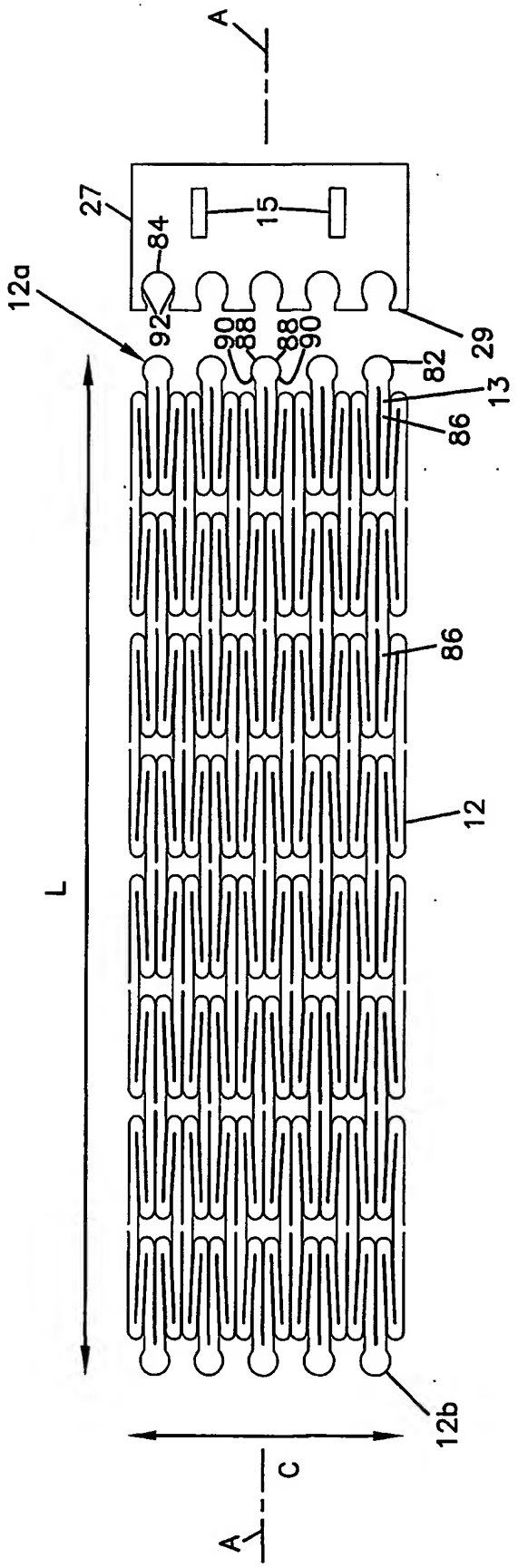


FIG.6A

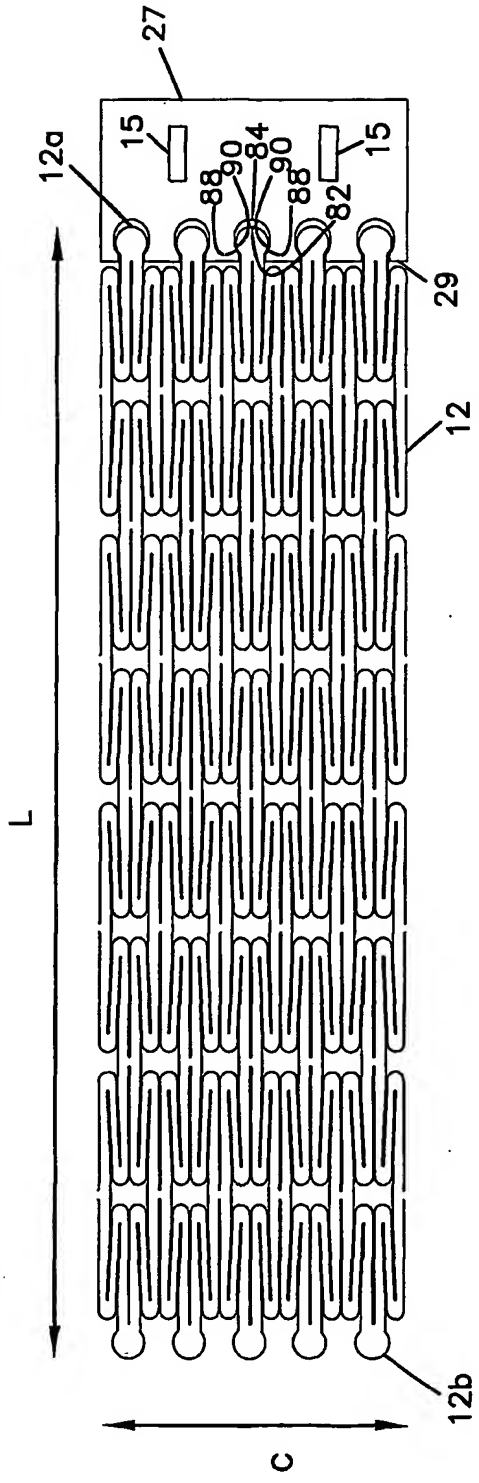


FIG.6B

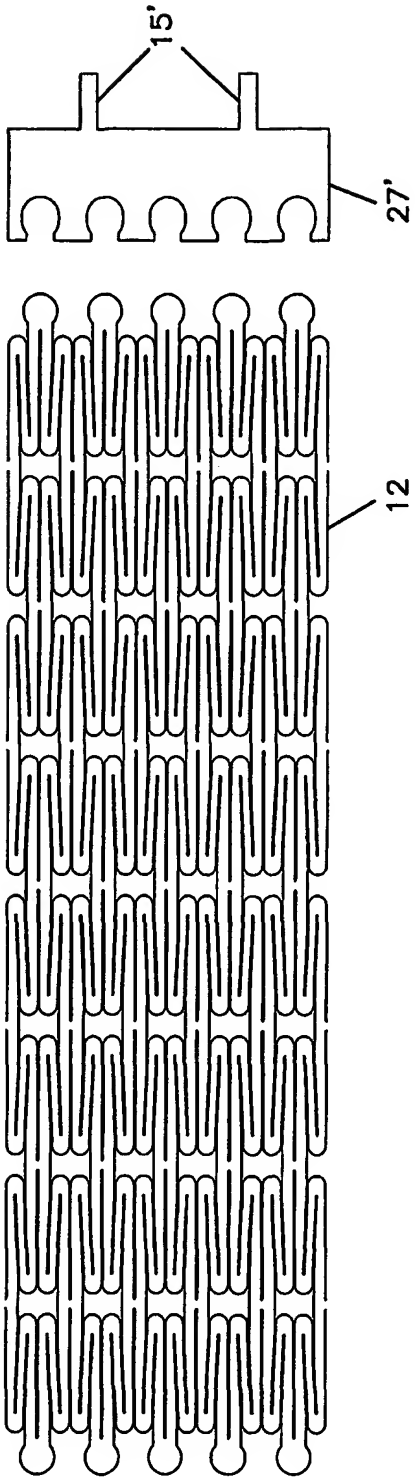


FIG. 7

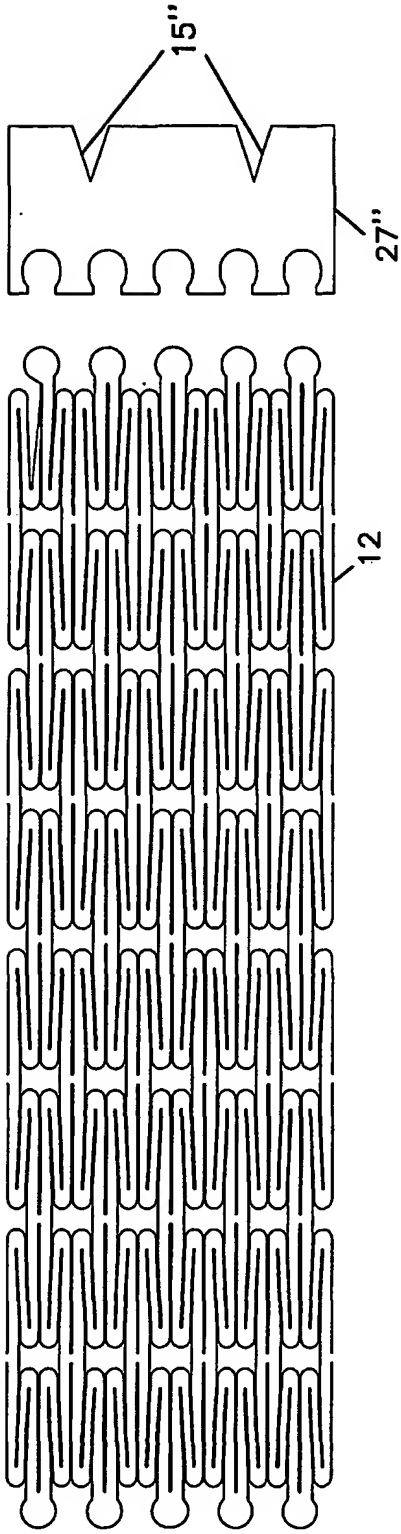
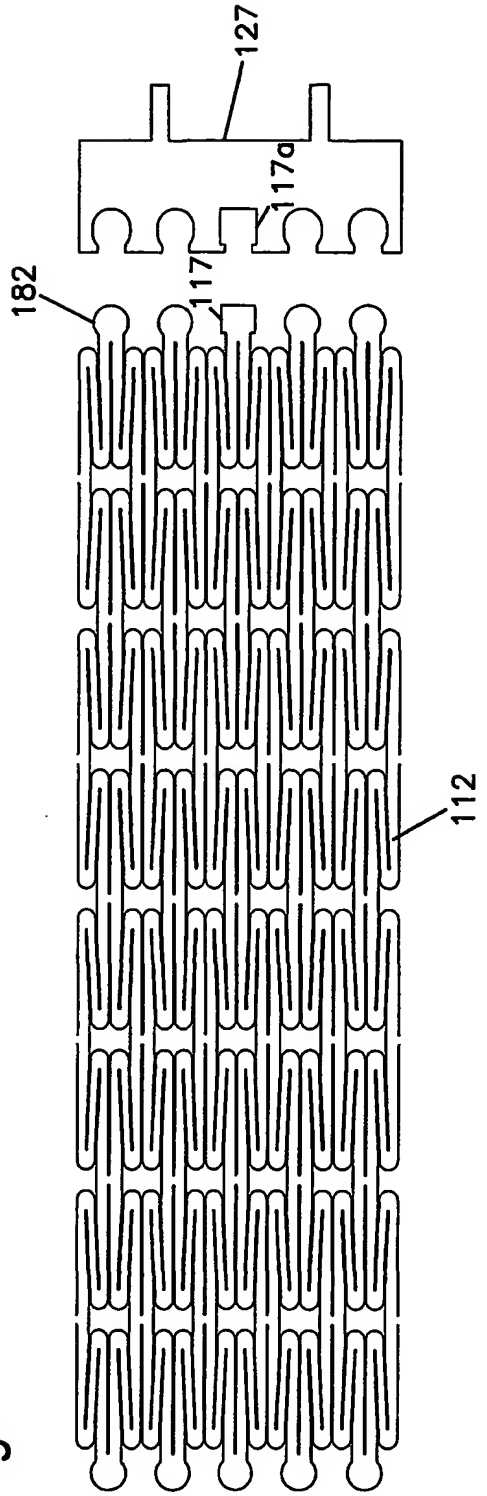


FIG. 8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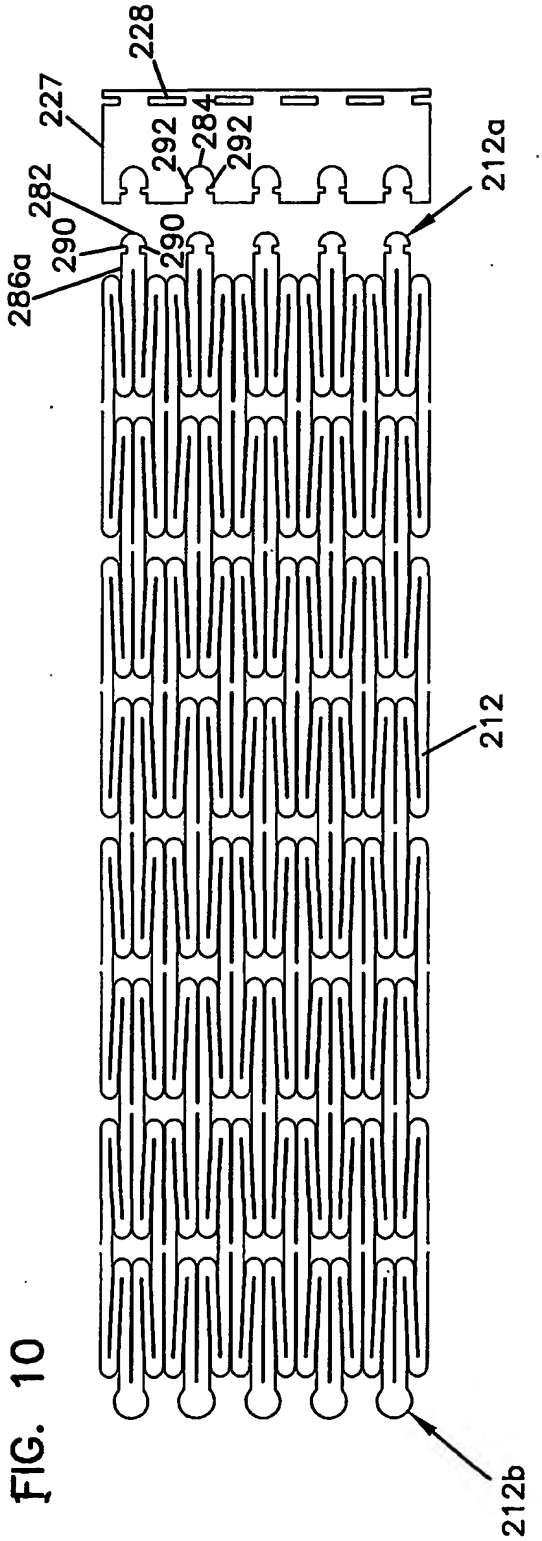
117a
182
117
112

FIG. 9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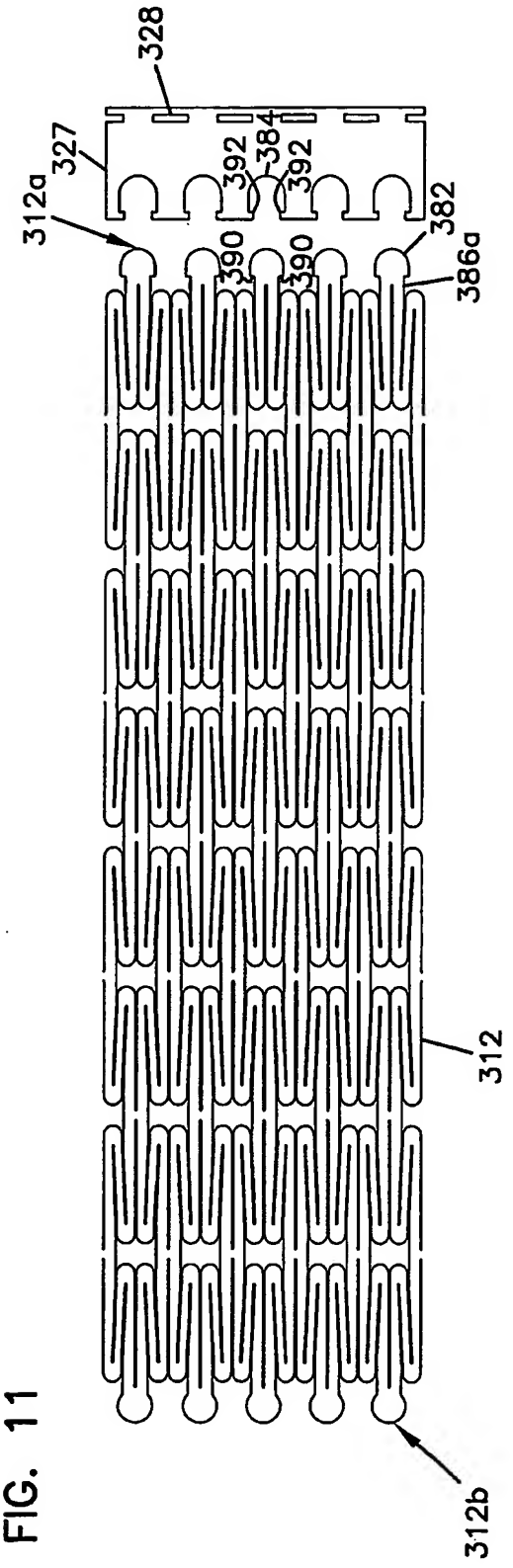
227
292
284
292
212a
282
290
290
286a
212
212b

FIG. 10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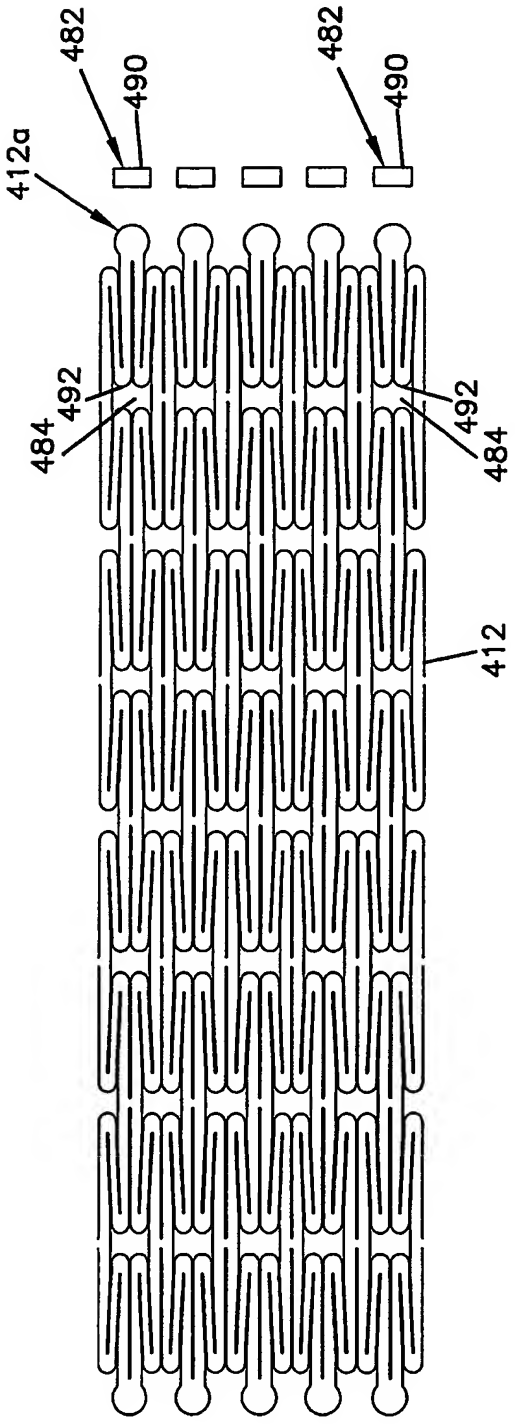
327
312a
392
384
392
382
390
390
386a
312
312b

FIG. 11


482
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482
490
412a
492
484
492
484
412

FIG. 12

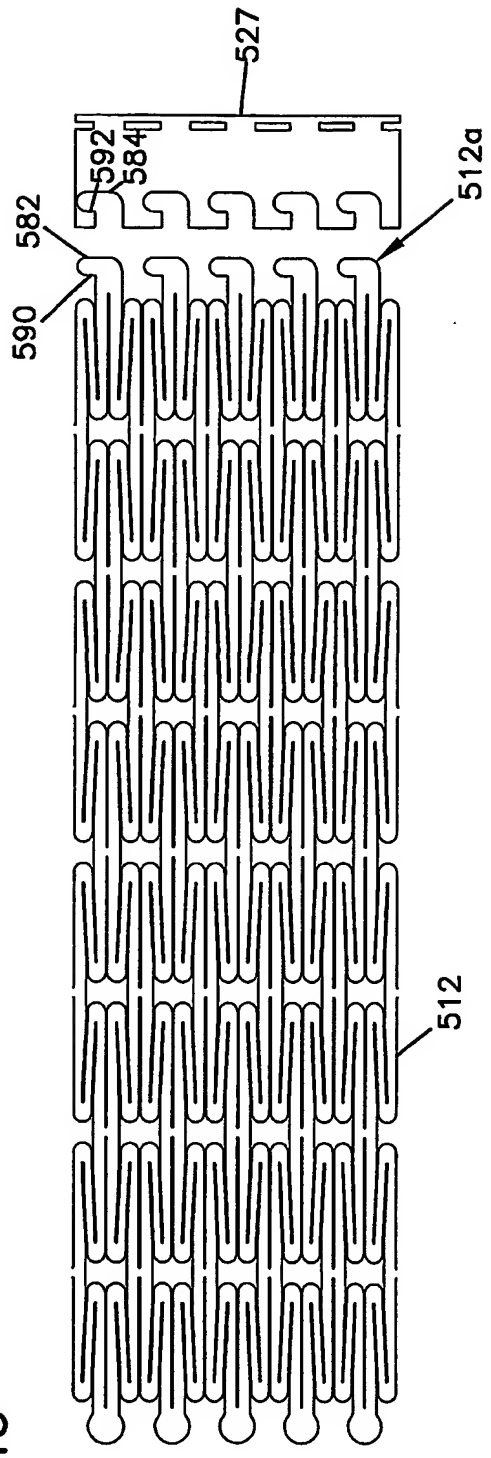

FIG. 13

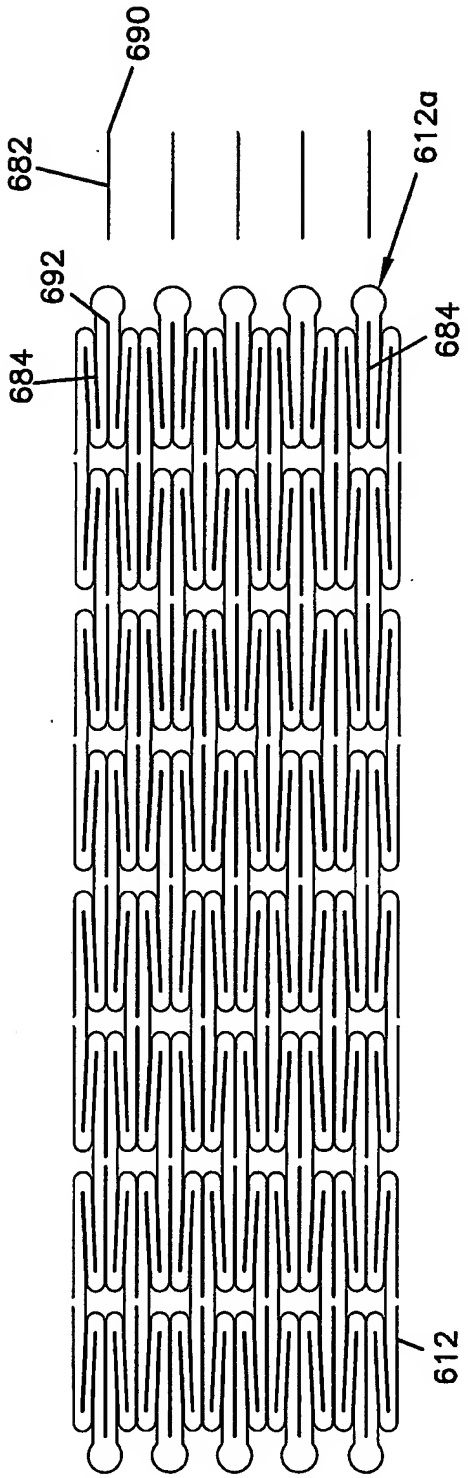

FIG. 14A

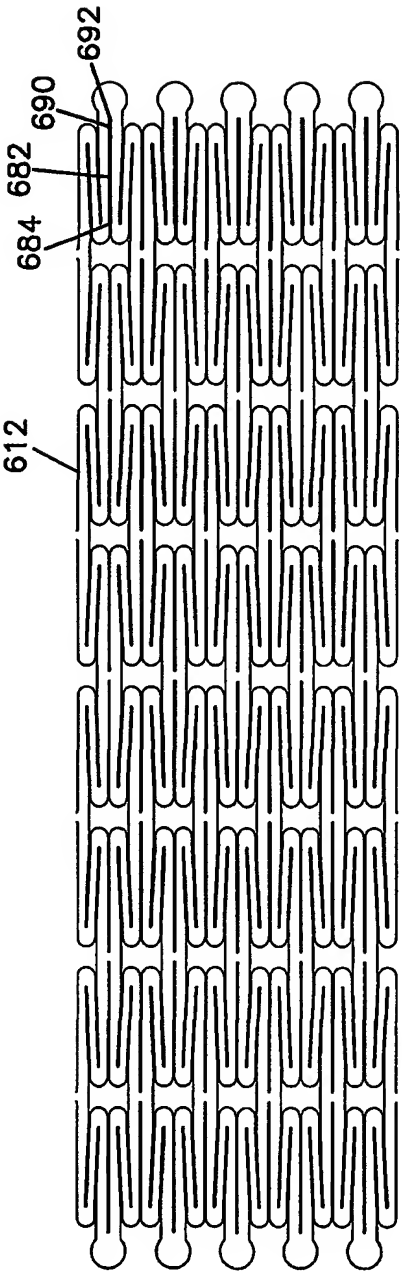

FIG. 14B

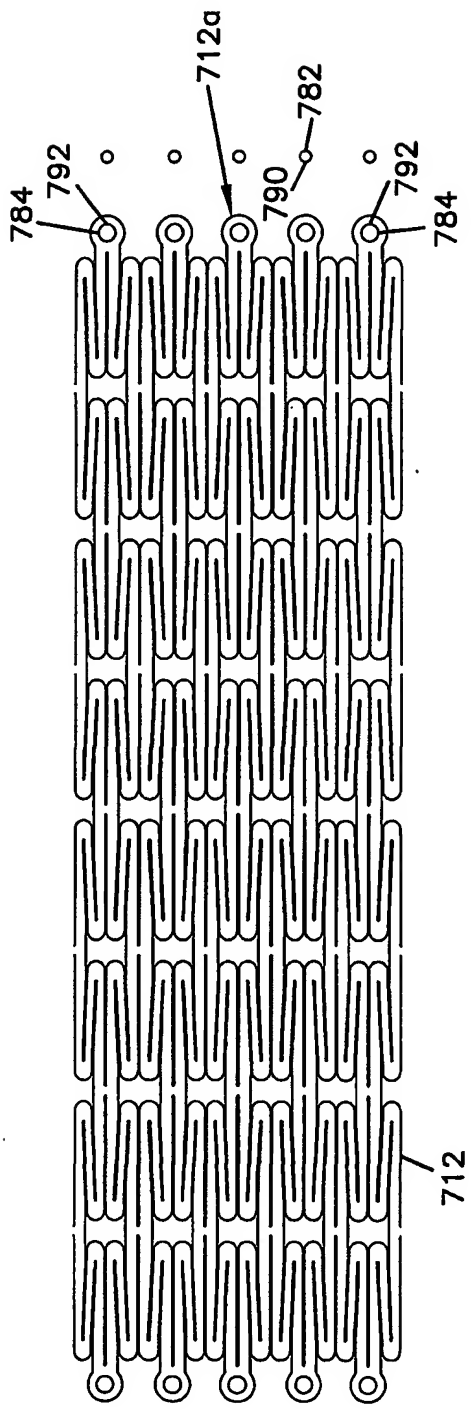

FIG. 15A

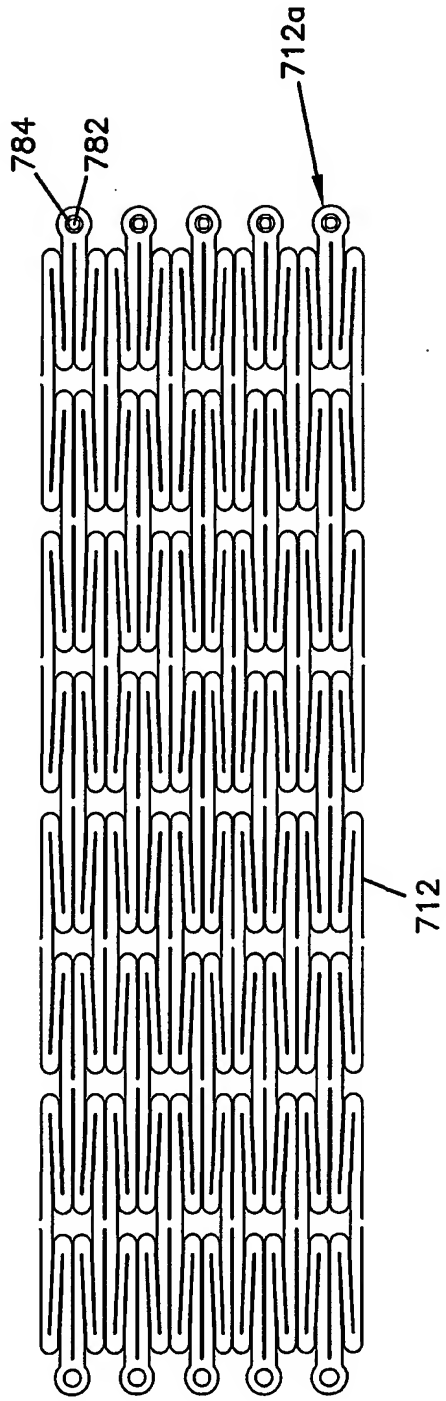

FIG. 15B

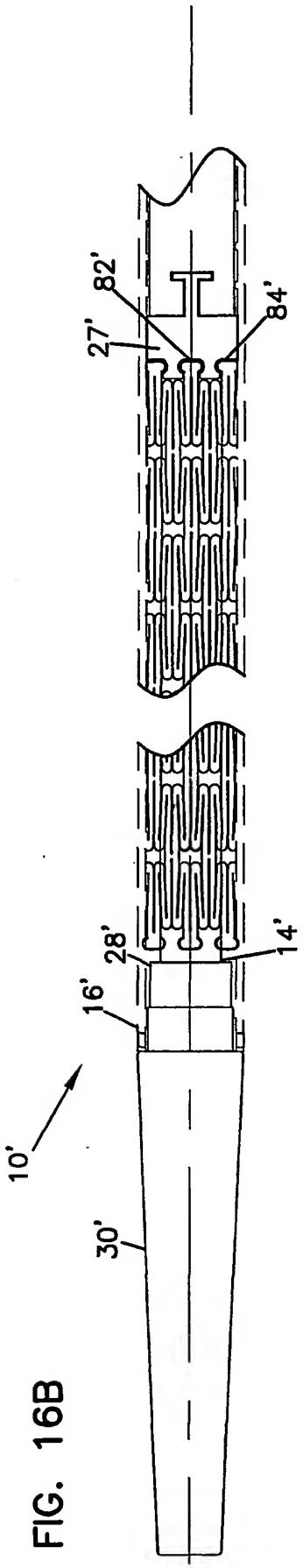

FIG. 16B

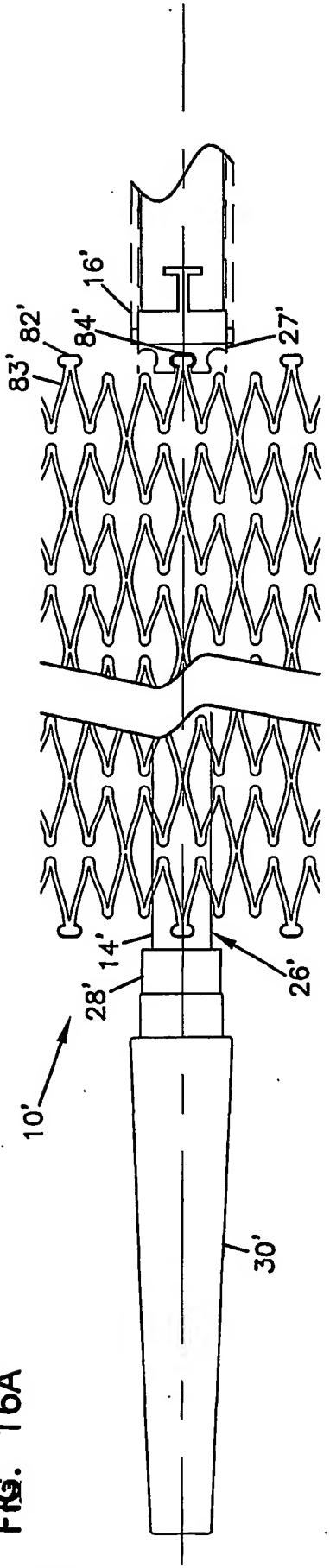

FIG. 16A

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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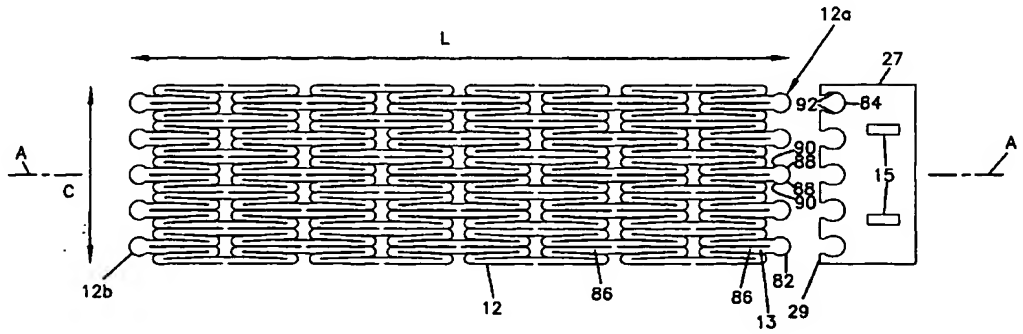
15 May 2003

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPLANT DELIVERY SYSTEM WITH INTERLOCK



(57) Abstract: An implant delivery system (10) is disclosed. The delivery system (10) includes an elongated member (14) having an implant mounting location (26). A self-expandable implant (12) is mounted at the implant mounting location (26). The implant (12) is held in a compressed orientation by a retractable sheath (16). An interlock structure (82, 84) prevents the implant (12) from deploying prematurely as the sheath (16) is retracted.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/03153

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 943 302 A (LENKER) 22 September 1999 (1999-09-22)	1,2,4,5, 18,19, 21-23, 26,27, 29-31, 34,36,38
Y	column 14, line 54 -column 18, line 13 column 24, line 10 - line 18; figures 1-5,16-19D	35
Y	US 6 004 328 A (SOLAR) 21 December 1999 (1999-12-21) column 6, line 42 -column 9, line 15; figures 2-4,4A,8A,8B	35

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 October 2002	11/10/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Germano, A

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 775 470 A (SCHNEIDER) 28 May 1997 (1997-05-28) column 6, line 6 -column 7, line 19; figures 1,2	35

INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 40-43
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 40-43

Claims 40 to 43 refer to a method for deploying a self-expandable implant. Such method comprises within its scope the method of implanting the implant in a living body, which is a method of treatment of the human or animal body by surgery. According to Art. 17(2)(a)(i), 17(2)(b) and Rule 39(1)(iv) the ISA is not required to perform the search for such subject-matter.

INTERNATIONAL SEARCH REPORT

nformation on patent family members

Int[redacted]tional Application No
PCT/US 02/03153

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